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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,119	02/26/2002	Arthur D. Gershowitz	032722-593	3521

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EXAMINER

KONTOS, LINA R

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 04/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/082,119

Applicant(s)

GERSHOWITZ, ARTHUR D.

Examiner

Lina Kontos

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 15 and 16 is/are pending in the application.
- 4a) Of the above claim(s) 9-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 15 and 16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Election/Restrictions

1.

This application contains claims directed to the following patentably distinct species of the claimed invention: Figures 1-3 pertaining to a retrograde cannula with infusion and stylet lumens and an expandable sealing member, and Figure 4 pertaining to a similar device and also incorporating a self-sealing member at the proximal end of the stylet lumen..

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Art Unit: 3763

During a telephone conversation with Alan Kopecki on April 1 a provisional election was made with traverse to prosecute the invention of Figures 1-3, claims 1-8,15, and16. Affirmation of this election must be made by applicant in replying to this Office action. Claims 9-14 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Specification

2.

The abstract of the disclosure is objected to because it contains a description of the non-elected claims. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3.

Claims 1,2,5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Cragg et al.

Cragg et al. teaches a balloon catheter comprising three lumens: one for accommodating a guiding mechanism (column 8, lines 45-46), a proximal lumen for the delivery of an agent to the patient's vasculature, and a third for the inflation of the balloon member (column 9, lines 47-49). Infusion lumen communicates with the interior of balloon sealing member (Figure 3) and

Art Unit: 3763

exit port, 60, in the wall of the balloon to facilitate the delivery of infusion fluid (column 10, line 23-24).

4.

Claims 15,16 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Neill et al.

O'Neill et al. teaches a coronary sinus catheter for the infusion of cardioplegia solutions comprising a multi-lumen catheter tube and a balloon wherein the catheter is inserted into the body (with a stylet therein) (column 12, line 32). The balloon is inflated, and the stylet removed from the catheter (column 12, lines 41-43) and then cardioplegia solution is infused into the patient via the catheter lumen (column 12, lines 49-50).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5.

Claims 3,4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cragg et al.

Cragg et al. discloses the claimed invention except that the lumens of the catheter are not coaxially oriented. It would have been obvious to one having ordinary skill in the art at the time of the invention was made to have the stylet lumen coaxially formed within the infusion lumen, since it has been held that rearranging parts of an invention involves only routine skill in the art.

In re Japikse, 86 USPQ 70.

Art Unit: 3763

6.

Claim 8 rejected under 35 U.S.C. 103(a) as being unpatentable over Cragg in view of O'Neill et al.

Cragg, as described above, teaches a multi-lumen catheter, but fails to teach a pressure-monitoring lumen.

O'Neill et al., as described above, teaches a multi-lumen catheter with an inflatable balloon assembly comprising an infusion, pressure-sensing, and inflation lumens (column 6, lines 37-38).

It would have been obvious to one skilled in the art at the time of the invention to incorporate a pressure-sensing lumen in the catheter device for the purposes of monitoring the pressure in the patient's vasculature.

Conclusion

7.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Patent 4,299,226 teaches a dual lumen catheter with an inflation balloon wherein the inner infusion lumen receives a stylet (column 1, lines 51-52) and the outer lumen of the catheter is used to inflate the balloon (column 1, lines 59-60).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lina Kontos whose telephone number is (703) 306-4207. The examiner can normally be reached on M-F 8:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

LRK
April 4, 2003


BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700